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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,535	11/09/2001	Nobunao Ikwaki	215051US0	5778

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EXAMINER

YOUNG, JOSEPHINE 8

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/986,535

Applicant(s)

IKEWAKI ET AL.

Examiner

Josephine Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☒ Claim(s) 1-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group I in Paper No. 7, received December 16, 2002, is acknowledged. The traversal is on the ground(s) that Group II, directed to methods for preventing or treating disease by using β -1,3-1,6-glucans, and Group III, directed to methods for sanitizing or protecting from contamination using β -1,3-1,6-glucans, are not patentable distinct using the criteria set forth in the Office Action mailed November 6, 2002. This is not found persuasive because while the modes of operation of Groups II and III may be the same, the methods of Groups II and III have different functions and different effects, and thus are not related. The function of Group II is directed to preventing or treating disease in a subject, such as a human, while the function of Group III is directed to sanitizing an object, such as equipment. Further, the effect of Group II is a subject that is, for example, cured of a disease. The effect of Group III is an object that is decontaminated. The method of one does not render obvious the method of the other.

Further, since the processes of use recited in Groups II and III are considered patentably distinct for their different functions and different effects, the related product recited in Group I is patentably distinct.

As set forth in the Office Action of November 6, 2002, searches for the three groups would not be co-extensive. The divergent nature of the methods based upon the different functions and effects indeed necessitates restriction in the instant case. A reference directed to treating or preventing a disease in a subject could not reasonably be expected to be a reference

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directed to sanitizing an object from contamination. Searching the three inventions constitutes a burdensome search, as a thorough search comprises a search of foreign patents and non-patent literature, as well as the appropriate U.S. patent classifications. To search the three independent and distinct inventions would indeed impose an undue burden upon the examiner in charge of this application.

Because these inventions are distinct and have acquired a separate status in the art as shown by their different classification and because of their recognized divergent subject matter, restriction for examination purposes is still deemed proper and is therefore made FINAL.

Accordingly, claims 16-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

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Specification

The disclosure is objected to because of the following informalities: β -1,3-1,6-glucan(s) is(are) referred to as β -1.3-1.6-glucan(s) throughout the specification. Appropriate correction is required.

Claim Objections

Claims 1-15 are objected to because of the following informalities: β -1,3-1,6-glucan is referred to as β -1.3-1.6glucan. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The β -1,3-1,6-glucan of claims 1-2 is a product of nature. It is recommended that Applicant amend the claims such that the product as claimed does not read on a product of nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11-12 are substantial duplicates of claim 10, drawn to food products comprising β -1,3-1,6-glucans that are differentiated only by intended use.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by HAMADA, Agric. Biol. Chem., 1983, 47 (6), 1167-1172.

HAMADA teaches that an acidic polysaccharide can be isolated from the culture broth of *Aureobasidium* sp. K-1. See abstract. HAMADA teaches on page 1170, left column, last sentence of the first paragraph, that this polysaccharide “consists of a backbone of β -1,3-linked glucose residues with β -linked single glucose units attached, roughly three out of four glucose residues at the O-6 positions in the backbone.” See also Figure 4 on the top of page 1171. Finally, on page 1167, right column, first complete sentence, HAMADA teaches that the polysaccharide produced under the disclosed conditions was about 4 mg per mL of broth.

Claims 1, 3, 5-6 and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by patent publication JP 06-340701 A to WATANABE et al.

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WATANABE teaches that β -glucans can be obtained by inoculating *Aureobasidium pullulans* IFO 4466 strain on a liquid medium. See Abstract. In the Figure with the Abstract, WATANABE discloses that the β -glucans are 1,3-1,6-glucans. Finally, WATANABE discloses that the β -glucan can be used in medicines, i.e. pharmaceutical compositions, and food additives, i.e. food products, by adding an organic solvent to the culture solution of *Aureobasidium pullulans* IFO 4466 strain.

Claims 1, 3, 5-6, 8 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by patent publication JP 62-205008 A to SHINOHARA et al.

SHINOHARA teaches glucans having β -1,3-1,6 bonds produced by liquid cultivation of an *Aureobasidium* species. See Abstract. SHINOHARA discloses that these glucans have improved film-forming, humectant, nonblocking, dispersing, nonadhesive, anti-inflammatory and nontoxic properties and thus can be used in cosmetics.

Claims 1, 3, 5-6, 8 and 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by patent publication JP 06-146036 A to HASEGAWA et al.

HASEGAWA teaches that β -1,3-glucans produced by microorganisms belonging to the genus *Aureobasidium* can be used as a metal surface detergent. See Abstract. In particular, HASEGAWA teaches that these β -1,3-glucans are β -1,3-1,6-glucans. See Formulas 1-4 of the specification.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over patent publication JP 06-340701 A to WATANABE et al. in view of the article FINKELMAN et al., Canadian Journal of Microbiology, 1987, 33 (2), 123-127.

Applicant claims a β -1,3-1,6-glucan isolated from *Aureobasidium* medium and a method to produce such β -1,3-1,6-glucan. In particular, Applicant claims a β -1,3-1,6-glucan from strain FERM P-18099, and methods to produce such β -1,3-1,6-glucan using said strain.

As set forth supra, WATANABE teaches that β -glucans can be obtained by inoculating *Aureobasidium pullulans* IFO 4466 strain on a liquid medium. See Abstract. In the Figure with the Abstract, WATANABE discloses that the β -glucans are 1,3-1,6-glucans. Finally, WATANABE discloses that the β -glucan can be used in medicines, i.e. pharmaceutical compositions, and food additives, i.e. food products, by adding an organic solvent to the culture solution of *Aureobasidium pullulans* IFO 4466 strain.

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WATANABE does not explicitly teach β -1,3-1,6-glucans from the FERM P-18099 strain of *Aureobasidium*, or methods to obtain β -1,3-1,6-glucans from such strain.

FINKELMAN teaches that *Aureobasidium pullulans* are known for their ability to synthesize large quantities of glucan. See page 123, left column, last paragraph. In particular, FINKELMAN teaches in that same paragraph that several distinct types of β -glucans can be isolated containing β -1,3 and β -1,6 linkages exclusively. On page 123, right column, first full paragraph, FINKELMAN teaches that the glucans containing these linkages comprise the majority of the structural components of the cell wall of *Aureobasidium*.

It would have been obvious to one of ordinary skill in the art to use any strain of *Aureobasidium* to obtain β -1,3-1,6-glucans, as it was well known, at the time the invention was made, that β -1,3-1,6-glucans are available in large quantities in *Aureobasidium*. Therefore, a skilled artisan would have been motivated and had a reasonable expectation of success of obtaining β -1,3-1,6-glucans from any strain of *Aureobasidium*, such as the strain of the present invention, FERM P-18099.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Conclusion

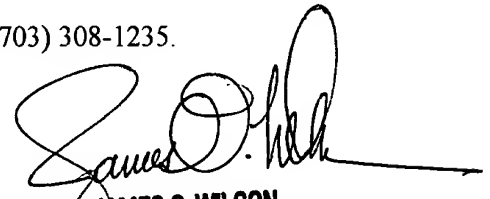
Claims 1-20 are pending. Claims 1-15 are rejected. Claims 16-20 are withdrawn. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Josephine Young whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JY
March 18, 2003


JAMES O. WILSON
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